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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,600	08/08/2005	Nicolas Aurio	N-32529A	7126
1095	7590	09/20/2007		
NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080			EXAMINER KOSAR, AARON J	
			ART UNIT 1651	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/516,600	Applicant(s) AURIO ET AL.	
	Examiner Aaron J. Kosar	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-51 is/are pending in the application.
- 4a) Of the above claim(s) 19-21, 29, 38-41, 44-46, 48-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-28, 30-37, 42 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/9/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group III (claims 22-28,30-37,39-40,42-43, and 45-46) and of the species of guar gum, collagen, and a metabolic syndrome, in the reply filed on August 2,2007 is acknowledged.

Applicant's instructions to amend the claims by requesting withdrawal of the claims of groups I, II, and IV and the arguments of traversal of group III is an implicit election of group III with traverse and has been interpreted as such.

The traversal is on the ground(s) that there is insufficient burden to restrict/elect among the claimed groups/species; however, this is not found persuasive because burden among the claims have been shown in that the combination of protein and fiber (the special technical feature) is known in the prior art and thus unity of invention is lacking. Since the claims/species do not share a special technical feature, each group (methods of making compositions comprising protein and fiber; methods of making compositions comprising protein-fiber compositions; protein-fiber compositions; and methods of using protein-fiber compositions) and each species is properly restricted.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-21,29,38,41,44,48-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Claims 39-40 and 45-46 do not read on the elected species and are withdrawn as being drawn to inventions of non-elected inventions.

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Applicant timely traversed the restriction (election) requirement in the reply filed on August 2, 2007.

Claims 22-28, 30-37, and 42-43 are pending and are examined on their merits.

Information Disclosure Statement

The information disclosure statement filed July 7, 2005 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the referenced documents cited have not been provided by the Applicant or the ISA. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Objections

Claim 27 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 27 does not require the selection of a gum, and thus permits the selection of mucilage, carrageenan, pectin, and β -glucan.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30 and 32-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "non-viscous" in claim 30 is a relative term which renders the claim indefinite. The term "non-viscous" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree of, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Applicant has reasonably demonstrated/disclosed that the claimed compound has viscosity; however, the claims also encompass non-viscous compounds which is clearly beyond the scope of the instantly disclosed/claimed invention. Please note that the term "non-viscous" is an absolute definition which means to stop from flowing and/or to render the visco-elastic properties constant in all instances and, thus, requires a higher standard for enablement than does "viscous" or specified values of viscosity, because everything has a degree of flow and thus a degree of viscosity which cannot be totally prevented.

Claims 24 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "0.01:1" and "20:1" in claims 24 and 32 are a relative term which render the claims indefinite. The terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Though the ratios are themselves unitless, various ratios can have various meanings depending upon the underlying components being compared, for example w/w, w/v, v/v, mol/mol, etc. Each ratio is a reasonable interpretation of

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the ratio and each embraces different subject matter, such that the metes and bounds of the claims are unclear, rendering the claims indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22, 26-28, 30, 34-37, 42, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Bell (A:PTO-892 3/26/07: US 6,210,686).

The claims are generally directed to a composition comprising one or more viscous soluble fibers and one or more viscosity-lowering proteins. The dependent claims are further drawn to the form of the composition (a drink) and the source of fiber and/or protein.

Bell teaches cholesterol level effecting composition (column 3, lines 50-62) that comprises fibers, including β -glucan (column 1, lines 44-58; column 3, lines 50-53), and protein, including whey protein, egg, and soy protein (column 5, lines 34-41). Bell also teaches that the composition includes a variety of product forms, including as a beverage or another oral composition (column 6, lines 41-44; column 7, line 26). Bell teaches that β -glucan from yeast has advantages over other forms of fiber; that yeast β -glucan functions to improve serum cholesterol levels (column 3 lines 50-62); and that the invention may also comprise individual or several ingredients including multiple proteins or fibers (column 5, lines 5-62).

Though Bell is silent regarding the elected species, Bell is applicable in demonstrating the unpatentability of the generic invention over the prior art.

Claims 22,23 26-28, 30,31, 34-37, 42, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by JAUSSAN (AU 9873118 A).

The general teachings of the claims are above. Additionally, the dependent claims are drawn to proportions/ratios of components and the rheological properties (viscosity) of the composition.

Jaussan teaches a diabetes-treating composition comprising a protein (from milk, whey, casein, soy, rice, pea, and/or oat protein (page 4, lines 28-33)) and a viscous soluble fiber (guar gum, xanthan gum, gum Arabic, pectin, and/or β -glucan (§5-6, page 3). Jaussan also teaches the composition has a viscosity of less than 500 mPa·s (1 Pa·s = 1 kg/m·s), including a composition having a viscosity of less than 0.04 kg/m·s, including 0.023 kg/m·s (§3, page 6; ¶1, page 9; ¶1, page 13) and blending the composition with water to form a liquid composition (pages 6-7). Jaussan teaches a composition having the 1.0 g soluble fiber (0.5g pectin or gum arabic per 100ml sample (page 4, line 26; examples 1 and 2) and 3.8 g per 100 mL casein:soy protein (1:1) (examples 1 and 2). Jaussan thus teaches a composition comprising a soluble fiber: (soy) protein ratio of between 0.01:1 and 20:1, by teaching a ratio of 0.26:1 (w/w) ($0.5:1.9 = 0.26:1$).

Though Jaussan is silent regarding the elected species of collagen, Jaussan is applicable in demonstrating the unpatentability of the generic invention over the prior art.

Claims 22, 25-27, 30, 33-36, and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by SHIMIZU (US #6,589, 511).

Shimizu teaches an orally administered (periodontal) composition comprising viscosity-modulating agents including the viscosity-increasing ingredients collagen and guar gum, including combining one or more of the members including collagen and guar gum (claim 12;

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column 4, ¶1). Shimizu also teaches that the viscosity-increasing agent (which includes the member guar gum) is from 0.05% to 10% by weight (claim 2).

Claims 22, 25-27, 30, 33-36, and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by LAUGHLIN (US #5,470,839).

Laughlin teaches an oral/enteric composition comprising guar (or gum arabic) and casein in the ratio of 0.15:1 (w/w) ($7/45 = 0.15/1$) (example, column 6-7). Laughlin also teaches the composition has a viscosity of 90cPs max (example, column 6-7).

Claims 22-28 and 30-37 are rejected under 35 U.S.C. 102(b) as being anticipated by OHTA (EP 0323510).

OHTA teaches a composition comprising a protein and fiber, including casein and carageenan in liquid form (page 5; figures 5 and 8). Ohta teaches that liquid form is maintained in contact with gastric juices when protein in the composition is below half as that of the fiber component (abstract, page 5 ¶1-2). Ohta teaches modifying the ratios of fiber:protein or 0.1:1 through 2:1 (example 5, page 12). OHTA also teaches modifying pH and temperature to affect viscosity, including effecting a viscosity below 100cPs, including less than 50cPs (figure 1). Ohta also teaches the formulation of the composition for food for diabetic/glucose-intolerant patients (page 18).

Claims 22, 26-28, 30, 34-37, and 42-43 are rejected under 35 U.S.C. 102(b) as being anticipated by HEATH (GB 2021948 A).

Heath teaches a composition comprising guar gum and a protein coating including the use of casein, soy, or gluten in the coating (column 1, claims).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22-28, 30-37, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over NAKAYAMA (US #6,287,623).

The general teachings of the claims are above.

Nakayama teaches a drink composition comprising a protein and gelling agent (claims 9, 19, and 29), including a composition comprising casein and agar (example 8). Nakayama teaches the food and drink composition having a viscosity of not greater than 20 centipoise (20cPs = 20mPa·s)(claims 9,19,29). Nakayama also teaches using gelling agents, including guar gum; varying/adding amounts of gelling agent; and using one or more proteins, including collagen/gelatin (columns 3, 6, and 7). Nakamaya also teaches modifying the composition based on the desired end product. In particular, Nakamaya teaches (a) optimizing the protein content to effect the desired smoothness of the product, including optimizing protein to be between 0.1 to 10% by weight and further optimizing to between 0.5 and 7% protein by weight (column 4, ¶4; column 6, ¶6); (b) optimizing the amount of gelling agent, including 0.1-1.0% (agar) by weight (column 6, ¶ 2); (c) direct measurement or, as needed to reduce viscosity in more viscous samples, dispersion with (500mL) water of a gelling-agent-containing drink compositions (column 7, ¶1-3); and (d) a ratio of fiber (gelling agent) to viscosity-lowering protein (protein) of 0.06:1 (see column 14, example 8: casein/agar = 0.26/3.6 = 0.06/1).

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To the extent that Nakayama is silent regarding the elected species combination of collagen and guar gum, it would have been obvious to one of skill to make a collagen-and-guar gum composition for the reasons below.

Please note that the terms that describe the species (e.g. guar gum) as a “gelling agent”, “viscosity-increasing agent”, “viscous, soluble fiber”, etc. presented below are relative descriptors of the intrinsic properties of each compound, such that, the compound (e.g. guar gum) is inseparable from its identity as a gelling agent, viscous soluble fiber, viscosity-increasing agent, etc.

Wherein Nakamaya teaches a liquid nutrient composition having protein and gelling agent comprising casein and agar (example 8), it would have been obvious to substitute the protein, casein, and gelling agent, agar, with collagen and guar gum, because Nakamaya teaches that any one or more proteins which may be used in food and drink may be used as the protein source, including collagen and/or casein(column 3, ¶1). Regarding the gelling agent, it would have been obvious to substitute agar with guar gum, because Nakamaya teaches that any suitable edible gelling agent may be used as the gelling agent source, including guar gum and/or agar (column 6, ¶3). One would have been motivated to substitute collagen and guar gum, because Nakamaya teaches a finite list of species of proteins/gelling agents, which includes collagen/guar gum, and because Nakamaya teaches that *any* one or more of these species may be used in the invention. One would have had a reasonable expectation of success in combining the compositions comprising collagen/guar gum, because Nakamaya teaches compositions comprising protein and gelling agent and because, absent evidence to the contrary, the success of

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the combination of the two components, including collagen and guar gum depends merely upon the independent properties as protein and gelling agent.

To the extent the claims are also drawn to the elected species of guar gum:collagen ratios and viscosity of guar gum and collagen comprising compositions, though Nakamaya is silent regarding the ratio of guar gum:collagen or the viscosity of the combination with this species, Nakamaya teaches the general benefit of varying the composition components which includes the benefit of enhancing the texture, taste, and feel of the compositions. Varying the component proportions would necessarily affect the viscosity of the composition and Nakamaya further teaches the benefit of producing a product which has a viscosity less than 20cPs has a desirable smoothness (column 7, ¶ 2) and effecting a variety of viscosities (liquids, jellies, etc) in product preparations (see examples 1-8).

Nakamaya is relied upon for the reasons discussed above. If not expressly taught by Nakamaya, based upon the overall beneficial teaching provided by this reference with respect reagent/component ratios and viscosity in the manner disclosed therein, the adjustments of particular conventional working conditions (e.g., determining the optimal ratios of components to effect a desirable viscosity), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

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From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Please note, since the Office does not have the facilities for examining and comparing Applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980), and "as a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

VISCOSTY (U:PTO-892: "Material/Approximate Viscosity" Viscosity Chart, <<http://www.research-equipment.com/viscosity%20chart.html>>, archived 4/11/2001, accessed online 9/12/2007.) teaches the general scale of viscosity of common material, including paste (150,000), honey (2,000-3,000 cPs), corn oil (50-100cPs), and water (1-5cPs).

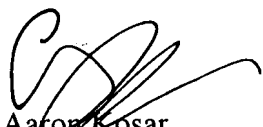
KONIG (EP 0855181 A2) teaches the use of soluble fibers with amino acids including protein (page 5 line 51), and soluble fiber including guar gum, pectin, xanthan gum, locust and ranges of fibre (page 6, ¶2) considered redundant to the 102(b) prior art presented above.

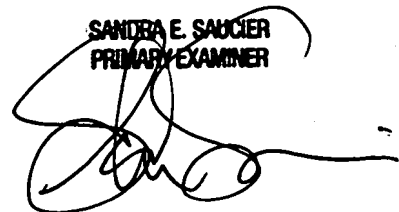
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron J. Kosar whose telephone number is (571) 270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Aaron Kosar
Examiner, Art Unit 1651


SANDRA E. SAUCIER
PRIMARY EXAMINER